CLAIMS

1. A plastid transformation vector for stably transforming a plastid, comprising, as operably-linked components, a first flanking sequence, a DNA sequence coding for a therapeutic human interferon (IFN), which is capable of expression in a plastid, and a second flanking sequence.

2. The vector of Claim 1, wherein said therapeutic human IFN further comprises a polyhistidine purification tag and a thrombin cleavage site.

3. The vector of Claim 1 further comprising a regulatory sequence.

4. The vector of Claim 3, wherein said regulatory sequence comprises a promoter operative in said plastid genome.

5. The vector of Claim 4, wherein said promoter is 16srRNA.

6. The vector of Claim 3, wherein said regulatory sequence comprises light regulated psbA 5', and psbA 3' elements.

7. The vector of Claim 1, stably integrated into a plastid genome of an edible plant.

8. The vector of Claim 7, wherein the edible plant is a low-nicotine tobacco plant or carrot plant.

9. The vector of Claim 8, wherein the low-nicotine tobacco plant is LAMD-609.

10. The vector of Claim 1, wherein the vector is competent for stabling integrating into a plastid genome of a plant cell and wherein the flanking DNA sequences are substantially homologous to sequences in a spacer region of said plastid genome.

11. The vector of Claim 10, wherein said spacer region is a transcriptionally active spacer region.

12. The vector of Claim 1, wherein the plastid is selected from the group consisting of chloroplast, chromoplast, amyloplast, proplastide, leucoplast and etioplast.

13. The vector of Claim 3, wherein said regulatory sequence further comprises a 5' untranslated region (5'UTR) capable of providing transcription and translation enhancement of said DNA sequence coding for therapeutic human interferon (IFN).

14. The vector of Claim 3, wherein said regulatory sequences further comprises a 3' untranslated region (3'UTR) capable of conferring transcript stability to said therapeutic human interferon (IFN).

15. The vector of Claim 1, wherein said first flanking sequence is trnI, and wherein said second flanking sequence is trnA.

16. The vector of Claim 15, wherein trnI and trnA provide for homologous recombination to insert an IFN containing cassette into the spacer region in an inverted repeat region of a chloroplast genome.

17. The vector of Claim 1, wherein said DNA sequence coding for therapeutic human interferon IFN is located in a single copy region of said plastid genome.

18. The vector of Claim 13, wherein said 5' UTR is a 5'UTR of psbA.

19. The vector of Claim 14, wherein said 3'UTR is a 3'UTR of psbA.

20. The vector of Claim 1, further comprising a DNA sequence encoding a selectable marker.

21. The vector of Claim 20, wherein said selectable marker is an antibiotic-free selectable marker.

22. The vector of Claim 21, wherein said antibiotic-free selectable marker is Betaine aldehyde dehydrogenase (BADH).

23. The vector of Claim 20, wherein said DNA sequence encoding a selectable marker encodes an antibiotic resistant selectable marker.

24. The vector of Claim 23, wherein said antibiotic resistant selectable marker is aadA.

25. A method for producing IFN comprising:

integrating the plastid transformation vector of Claim 1 into the plastid genome of a plant cell; and

growing said plant cell to thereby express said IFN.

26. The method of Claim 25, wherein said IFN is competent to produce an immunogenic response in a mammal.

27. The method of Claim 26, wherein said immunogenic response is substantially free of negative side effects associated with injected IFN.

28. An isolated and purified IFN, competent to produce and immunogenic response in a mammal.

29. The isolated and purified IFN of Claim 28, wherein said IFN is configured in a monomeric form.

30. The IFN of Claim 29, wherein said IFN is configured in a multimeric form.

31. The IFN of Claim 29, wherein said IFN is a structural equivalent to natural human IFN.

32. An orally administerable therapeutic human interferon IFN, suitable for oral administration to a mammal.

33. A method for variable-expressing IFN comprising:

integrating a plastid transformation vector according to Claim 1 into a plastid genome of a plant cell; and

growing said plant cell to express said recombinant therapeutic human interferon IFN.

34. The method of Claim 33, further comprising:

extracting IFN from leaves of a stably transformed plant isolating IFNα2b from other plant proteins.

35. A plant stably transformed with the transformation vector of Claim 1.

36. A progeny of the plant of Claim 35.

37. A seed of the plant of Claim 35.

38. A part of the plant of Claim 35, comprising a plastid including said DNA sequence coding for therapeutic human interferon IFN.

39. The plant of Claim 35, wherein said plant is an edible plant suitable for mammal consumption.

40. The plant of Claim 39, wherein said edible plant is LAMD-609.

41. The plant of Claim 35, wherein said plant further comprises at least one chloroplast transformed with the vector of Claim 1.

42. The plant of Claim 35, wherein said plant further comprises mature leaves transformed with the vector of Claim 1.

43. The plant of Claim 35, wherein said plant further comprises young leaves

transformed with the vector of Claim 1.

44. The plant of Claim 35, wherein said plant further comprises old leaves transformed with the vector of Claim 1.

45. The plant of Claim 40, wherein the expression of IFN is at least about 6.0 percent total soluble protein.

46. The plant of Claim 40, wherein said expression of IFN in said edible plant is about 12.5 percent total soluble protein.

47. The plant of Claim 35, wherein said plant is Nicotiana tabacum cv. Petit Havana.

48. The plant of Claim 47, wherein the expression of IFN in said Nicotiana tabacum cv. Petit Havana is at least 4.0 percent total soluble protein.

49. The plant of Claim 47, wherein the expression of IFN in said Nicotiana tabacum cv. Petit Havana is about 18.5 percent total soluble protein.

50. A method of producing a biopharmaceutical protein of interest in a low-nicotine tobacco plant comprising:

obtaining low-nicotine tobacco plant plastid,

transforming said plastid with an expression vector comprising a nucleic acid that encodes said biopharmaceutical protein of interest,

expressing said biopharmaceutical protein in said plastid, and

recovering said biopharmaceutical protein of interest.

52. A plastid transformation vector for a stably transforming a plastid genome, comprising, as operably-linked components, a first flanking sequence, a DNA sequence coding for a therapeutic human interferon IFN or a substantially homologous DNA sequence of therapeutic human interferon IFN, wherein the therapeutic human interferon IFN is operably linked to a polyhistidine purification tag and a thrombin cleavage site, and a second flanking sequence.

53. The plastid transformation vector of claim 1, wherein said IFN is IFNα2b.